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International application number: PCT/US05/001525

International filing date: 12 January 2005 (12.01.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US  
Number: 60/536,008  
Filing date: 12 January 2004 (12.01.2004)

Date of receipt at the International Bureau: 03 March 2005 (03.03.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



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APPLICATION NUMBER: 60/536,008

FILING DATE: *January 12, 2004*

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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No. EV343594097US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
J. Nelson	Wright	Mercer Island, WA
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto		
TITLE OF THE INVENTION (500 characters max)		
INSTRUMENTS HAVING WIRELESS LOCALIZATION TRANSPONDERS FOR PERFORMING MEDICAL PROCEDURES		
CORRESPONDENCE ADDRESS Direct all correspondence to Customer Number:		25096
<input type="checkbox"/> Firm or Individual Name	Perkins Coie LLP	
ENCLOSED APPLICATION PARTS (check all that apply)		
<input checked="" type="checkbox"/> Specification Number of Pages 6 <input type="checkbox"/> CD(s), Number		
Appendix A (101 pgs); Appendix B (44 pgs); Appendix C (32 pgs); Appendix D (22 pgs); Appendix E (28 pgs); Appendix F (61 pgs)		
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets 3 <input checked="" type="checkbox"/> Other (specify): Postcard, Check No. 4784 (\$80)		
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<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. <input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any deficiency in filing fees or credit any overpayment to Deposit Account Number: 50-0665 <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.		FILING FEE AMOUNT (\$) \$80
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. <input checked="" type="checkbox"/> No. <input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____		

Respectfully submitted, PTP  
SIGNATURE

Date January 12, 2004

TYPED or PRINTED NAME Paul T. ParkerREGISTRATION NO. 38,264  
(if appropriate)TELEPHONE (206) 359-8000Docket Number: 341148024US**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INSTRUMENTS HAVING WIRELESS LOCALIZATION TRANSPONDERS FOR  
PERFORMING MEDICAL PROCEDURES**

**APPLICATION(S) INCORPORATED BY REFERENCE**

[0001] The following pending U.S. Patent Applications are incorporated herein in their entirety by reference: 10/416,827 (Appendix A); 09/954,700; 10/213,950; 10/679,801 (Appendix B); 10/382,123 (Appendix C) 10/334,658 (Appendix D); application entitled "IMPLANTABLE MARKER WITH WIRELESS SIGNAL TRANSMITTER," filed on December 24, 2003 (Perkins Coie LLP Docket No. 34114.8013US00 – Appendix E); and application entitled "RECEIVER USED IN MARKER LOCALIZATION SENSING SYSTEM," filed on December 31, 2003 (Perkins Coie LLP Docket No. 34114.8018US00 Appendix F).

**TECHNICAL FIELD**

[0002] The present application is related to catheters, electrodes and other instruments used for surgical applications (e.g., minimally invasive), neurostimulation, cardiac electrophysiology, and other applications.

**BACKGROUND**

[0003] Many medical procedures involve locating an electrode, scalpel or other instrument within a patient. For example, electrodes for cardiac defibrillation and/or pacing are positioned in and/or near the heart to deliver electrical stimulation along selected vectors, or electrodes for neurostimulation can be implanted near the spine for treating pain or in deep brain locations for treating epilepsy, movement disorders and other disorders. Other procedures, such as minimally invasive surgeries, position a scalpel, ablation tip or other device proximate to the treatment area within the patient. In many of these applications,

it is important to determine and track the location of the tip of the catheter for accurately locating the therapy device at the internal treatment area in the patient.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0004] Figure 1 is a partial cross-sectional view of an instrument having a wireless localization transponder.
- [0005] Figure 2 is a schematic view of the distal end of the instrument shown in Figure 1 in use in a cardiac application.
- [0006] Figure 3 is a side view of an electrode for deep brain stimulation.

#### DETAILED DESCRIPTION

- [0007] Figure 1 is a partial cross-sectional view of an instrument 10 for performing a minimally invasive surgery, electrode implantation/extraction, or other minimally invasive procedures. The embodiment of the instrument 10 shown in Figure 1 includes a handle 12 and a flexible member 14 extending from the handle. The flexible member 14 can be a catheter having a lumen or a solid body. The flexible member 14 is configured to be inserted into the patient and to travel within the vasculature, throat, respiratory passageways, intestinal tracts or other parts of the patient. The flexible member 14, for example, can be configured to be inserted into the vasculature through an incision, and then moved through the vasculature to position the distal portion of the flexible member 14 at a desired treatment site within the patient.
- [0008] The instrument 10 also includes an operative element 18 carried by the flexible tube. The operative element 18 can be a scalpel, stimulation electrode, sensor, ablation electrode, optical member (e.g., optical fiber/light source), radiation source, or other feature for performing a procedure. The operative element 18 can be coupled to an energy source, fluid system or other device by a line 19 extending at least partially through the flexible member 14. The line 19, for example, can be an electrical lead when the operative element 18 is an electrode contact to transmit electrical current to/from the electrode contact. The

operative element 18 is generally located at a distal region of the flexible body 14 relative to the handle 12.

[0009] The instrument 10 also includes a wireless marker 20 that wirelessly transmits a localization signal in response to a wirelessly transmitted excitation energy. The wireless marker 20, for example, can be a small magnetic resonator that produces an alternating magnetic field in response to an alternating excitation field. Suitable magnetic transponders and the systems for producing the excitation fields, processing the signals from the transponders, and computing the location of the transponder are described in the foregoing applications incorporated by reference and/or attached in Appendices A-F. The wireless marker 20 can be identical to any of the markers disclosed in Appendices A-F, but it does not necessarily need to be encapsulated in a separate capsule or housing. For example, the wireless marker 20 can include a core 22, a coil 24 and a capacitor 26 electrically coupled to the coil 24 without a separate capsule. The marker 20 can accordingly be embedded in the flexible member 14 without additional encapsulation. Alternatively, the marker 20 can also be encapsulated in a separate capsule as shown in Appendices A-F. When the marker 20 is encapsulated in a separated capsule, it can be attached to an external portion of the flexible member 14 or embedded in the flexible member 14.

[0010] Figure 2 illustrates an example of using the instrument 10 for cardiac electrotherapy, such as cardiac monitoring, ablation, pacing and/or defibrillation. In this embodiment, the flexible member 14 is inserted into the femoral artery and guided to the inferior vena cava using the localization signal from the marker 20 and/or other guidance techniques (e.g., guide wire). From the inferior vena cava, the operative element 18 at the distal tip of the flexible member 14 is located in or proximate to a desired location of the heart for the specific treatment. The instrument 10 can be inserted into other vessels for placing the operative element at different locations in or proximate to the heart or other body part in a similar manner.

[0011] Figure 3 illustrates a different embodiment of an electrode 100 for deep brain stimulation. In this embodiment, the electrode 100 has a shaft 110, a plurality of electrode contacts 112a-c, and a lead wire electrically coupled to the electrode contacts 112a-c. The electrode 100 can alternatively have only a single electrode contact. The shaft 110 is generally rigid, but it can be flexible in certain embodiments.

[0012] The electrode 100 also includes a wireless marker 20. In this embodiment, the wireless marker 20 is carried at the distal end of the shaft 110, but it can be located at a different region of the shaft 110. The location of the electrode contacts 112a-c can be determined relative to an internal stimulation site within the brain by computing the location of the marker 20 as set forth in Appendices A-F. As such, the electrode contacts 112a-c can be accurately positioned within the brain proximate to the neurons that are to be stimulated. In one embodiment, the marker 20 guides the electrode 110 to position the electrode contacts 112a-c proximate to the vagus nerve, but it will be appreciated that the electrode 100 can be configured for use in many other applications to stimulate other nerves.

[0013] From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

## CLAIMS

I/We claim:

- [c1] 1. An instrument for performing an invasive procedure in a patient, comprising:
  - a body configured to pass through an internal portion of the patient;
  - an electrode contact on the body;
  - a lead extending along the body and coupled to the electrode contact; and
  - a wireless marker carried by the body, the wireless marker having a transponder that produces a wirelessly transmitted signal in response to a wirelessly transmitted excitation energy for determining the position of the marker in a reference frame.
- [c2] 2. The instrument of claim 1 wherein the body is a flexible member configured to pass through vasculature of the patient.
- [c3] 3. The instrument of claim 1 wherein the body is a flexible member configured to pass through at least a portion of the patient.
- [c4] 4. The instrument of claim 1 wherein the body is a shaft configured to be inserted into the patient.
- [c5] 5. The instrument of claim 4 wherein the shaft is rigid.
- [c6] 6. The instrument of claim 4 wherein the shaft is rigid and configured to be implanted in the brain of the patient.

[c7]        7. The instrument of claim 1 further comprising a plurality of electrode contacts on the body, wherein the lead has a plurality of electrode wires individually attached to different electrode contacts.

[c8]        8. An instrument for performing a minimally invasive procedure in a patient, comprising:  
              a flexible member configured to pass through an internal portion of the patient;  
              an operative element carried by the flexible member; and  
              a wireless marker carried by the flexible member, the wireless marker having a transponder that produces a wirelessly transmitted signal in response to a wirelessly transmitted excitation energy for determining the position of the marker in a reference frame.

[c9]        9. The instrument of claim 8 wherein the flexible member is a catheter.

[c10]       10. The instrument of claim 9 wherein the operative element is at least one of an electrode contact, a sensor, a scalpel, an ultrasound emitter and/or a radiation source.

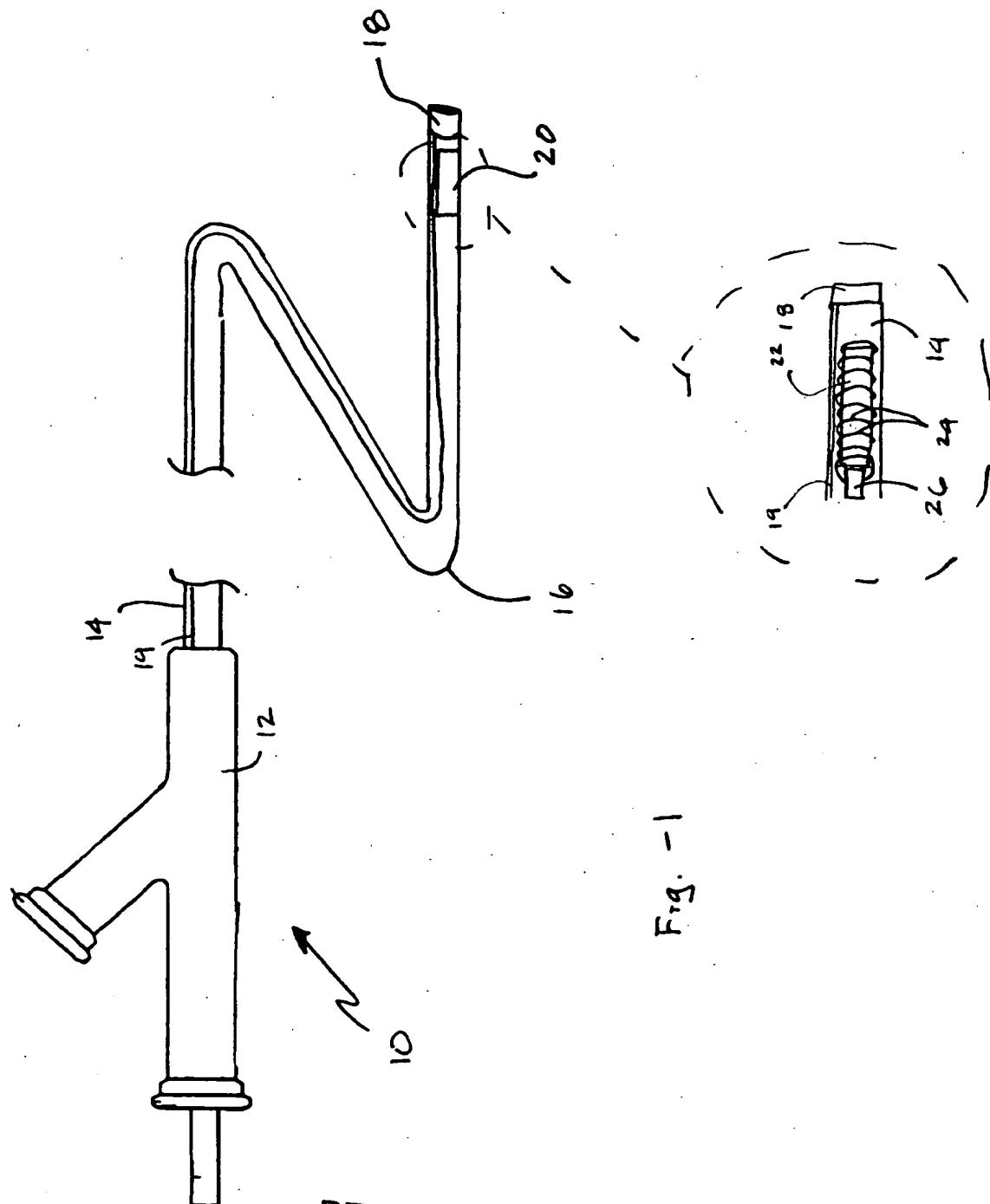
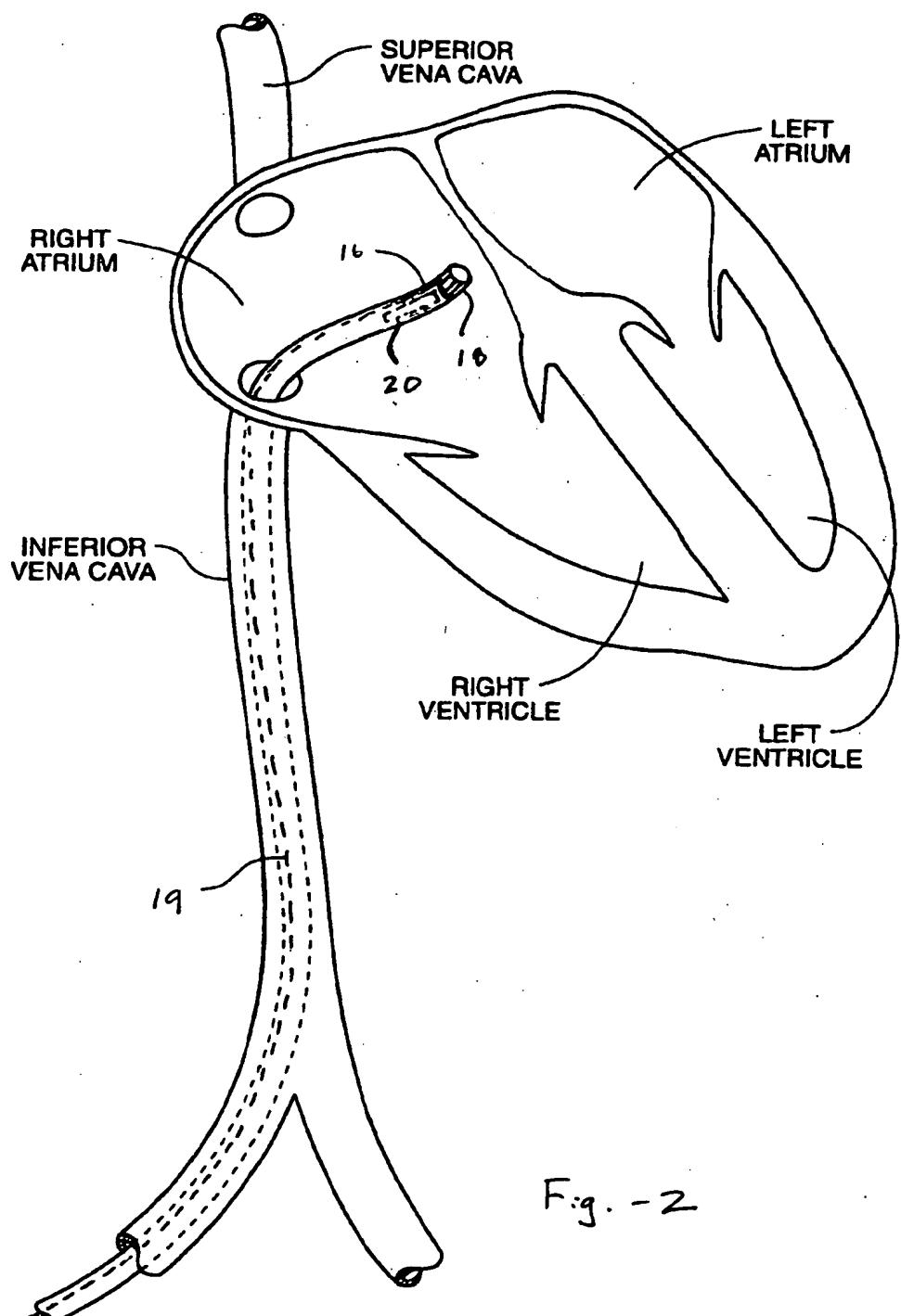


Fig. -1

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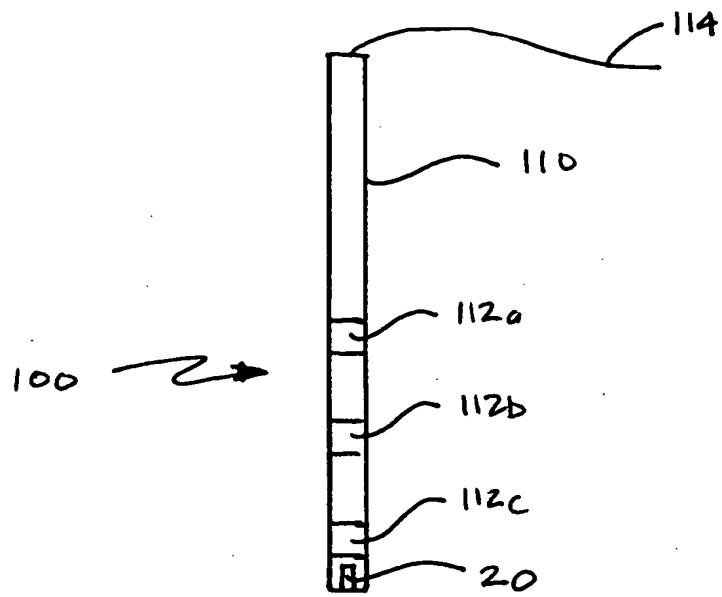


Fig. -3

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